

Original Contribution

A Comparative Effectiveness Evaluation of Percutaneous Adhesiolysis and Epidural Steroid Injections in Managing Lumbar Post Surgery Syndrome: A Randomized, Equivalence Controlled Trial

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Background: Speculated causes of post lumbar surgery syndrome include epidural fibrosis, acquired stenosis, and facet joint pain among other causes. Even though fluoroscopically directed caudal epidural injections and facet joint interventions are effective in some patients, others continue to suffer with chronic persistent pain. Percutaneous adhesiolysis with target delivery of medications has been demonstrated to be effective in these patients. However, the evidence for percutaneous adhesiolysis in managing post surgery syndrome has been questioned, coupled with a paucity of controlled trials.

Study Design: A randomized, equivalence, controlled trial.

Setting: An interventional pain management practice, a specialty referral center, a private practice setting in the United States.

Objectives: To evaluate the effectiveness of percutaneous epidural adhesiolysis in patients with chronic low back and lower extremity pain in post surgery syndrome and compare with fluoroscopically directed caudal epidural steroid injections.

Methods: Patients were randomly assigned to one of 2 groups: Group I (60 patients) receiving caudal epidural injections with catheterization up to S3 with local anesthetic, steroids, and 0.9% sodium chloride solution serving as the control group, and Group II (60 patients) receiving percutaneous adhesiolysis with targeted delivery of lidocaine, 10% hypertonic sodium chloride solution, and non-particulate Betamethasone serving as the intervention group. Randomization was performed by computer-generated random allocation sequence by simple randomization.

Outcomes Assessment: Multiple outcome measures were utilized including the Numeric Rating Scale (NRS), the Oswestry Disability Index 2.0 (ODI), employment status, and opioid intake with assessment at 3, 6, and 12 months post treatment.

Significant pain relief was described as 50% or more, whereas significant improvement in the disability score was defined as a reduction of 40% or more.

Results: Significant pain relief ($\geq 50\%$) and functional status improvement was recorded in 73% of patients in Group II versus 12% in Group I ($P < 0.001$). The average procedures per year were 3.5 with an average total relief of 42 out of 52 weeks in Group II and 2.2 procedures with total relief per year of 13 weeks in Group I ($P < 0.001$).

Limitations: The results of this study are limited by potentially inadequate double blinding, by the lack of a placebo group, and the preliminary report of one-year follow-up.

Conclusions: Percutaneous adhesiolysis in chronic function-limiting, recalcitrant low back pain in post lumbar surgery syndrome demonstrated effectiveness in 73% of the patients.

Key words: Post lumbar surgery syndrome, post lumbar laminectomy syndrome, chronic low back pain, epidural adhesions, epidural steroid injections, percutaneous adhesiolysis, epidural fibrosis, spinal stenosis, randomized trial, comparative effectiveness

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Failed back surgery syndrome or post surgery syndrome, a cluster of syndromes following spine surgery with persistent pain and disability (1-9), has been reported with increasing frequency, simultaneously with increased surgical volume (9-17). Further, overall chronic persistent low back pain has been reported to be increasing (18,19). Consequently, health care expenditures have been increasing substantially over the years with an increase of interventional techniques performed to manage various types of low back pain including the pain resulting from post lumbar surgery syndrome (9,20-23).

The continued pain and disability in the low back and lower extremities following lumbar spine surgery has been hypothesized to be secondary to multiple causes including epidural fibrosis, acquired stenosis, sacroiliac joint pain, and facet joint pain (1-5,24-32). Post surgery syndrome pain can be treated with interventional techniques in patients non-responsive to conservative management (1,2,24-42). An examination of the literature shows that epidural fibrosis may account for as much as 20% to 36% of all cases of failed back surgery syndrome (1,2,4,5,24,42-45). However, a correlation between peridural scarring and radicular pain (4,43-45) and poor clinical outcomes (46) has been reported by some authors, while others (47-49) have contradicted the role of epidural fibrosis as a causative factor.

Post-surgery syndrome, non-responsive to conservative management with rehabilitation techniques and medication, is managed by epidural injections (28,31,32), percutaneous adhesiolysis (1,2,24,25,29,36,50-58), spinal endoscopic adhesiolysis (1,2,24,25,29,54,59), therapeutic facet joint nerve blocks (60,61), sacroiliac joint injections (24,41), spinal cord stimulation (62-66), intrathecal implantable systems (67), and finally repeat surgery (68). The evidence for managing post surgery syndrome has been determined to be variable based on inclusion criteria. Caudal epidural injections have been shown to have an evidence of Level II-1 (32), percutaneous adhesiolysis in patients after failure of caudal epidural injections Level I (1,2), spinal cord stimulation Level II-1 or II-2 (66), and implantable intrathecal drug administration systems Level II-3 or Level III (67).

Interventional techniques for managing chronic low back pain are commonly performed; however, there has been significant criticism of most of these procedures (69-73). The purpose of percutaneous epidural lysis of adhesions is to eliminate the deleterious

effects of scar formation, which can physically prevent direct application of drugs to nerves or other tissues, and to ensure delivery of high concentrations of injected drugs to the targeted areas (1,2,24,25,36).

This study is designed as a comparative effectiveness evaluation of percutaneous adhesiolysis and epidural steroid injections in managing lumbar post surgery syndrome in a randomized, equivalence, controlled trial.

METHODS

The study was conducted in an interventional pain management practice, a specialty referral center, in a private practice setting in the United States. The study was performed based on Consolidated Standards of Reporting Trials (CONSORT) guidelines and an extension of the CONSORT statement reporting non-inferiority and equivalence in randomized trials (74,75). The study protocol was approved by the Institutional Review Board (IRB) and registered on the U.S. Clinical Trial Registry with an assigned number of NCT00370994.

Participants

The study was designed to assign 200 patients to one of 2 groups. Group I patients received an epidurogram (with RK 15-gauge needles) followed by passage of a Racz® catheter 19 gauge Brevi-STF up to S3 followed by injection of 5 mL of 2% preservative-free lidocaine in the operating room and injection of 6 mL of 0.9% sodium chloride solution, 6 mg of non-particulate Betamethasone, and 1 mL of sodium chloride solution and removal of the catheter in the recovery room. Group II patients received adhesiolysis and targeted placement of Racz catheter with injection of 5 mL of 2% preservative-free lidocaine, followed by 6 mL of 10% sodium chloride solution and 6 mg of non-particulate Betamethasone and 1 mL of sodium chloride solution. Injections were similar in consistency and color in both groups. The differences in Group I and Group II were the position of the catheter (at S3 versus targeted), adhesiolysis (versus lack of adhesiolysis), and injection of 10% vs 0.9% sodium chloride solution.

Group I functioned as the control group receiving caudal epidural injections since no adhesiolysis was performed and there was no injection of 10% sodium chloride solution.

Interventions

All patients were provided with the IRB-approved protocol and informed consent which described in de-

tail all aspects of the study and withdrawal process. Summary of steps and procedural considerations are illustrated in Table 1.

Pre-Enrollment Evaluation

The pre-enrollment evaluation included collection of demographic data, medical and surgical history with co-existing disease(s), radiologic investigations, physical examination, pain rating scores using the NRS, work status, opioid intake, and functional status assessment by ODI.

Inclusion Criteria

Inclusion criteria were a history of lumbar surgery of at least 6 months duration in the past; patients over the age of 18 years; patients with a history of chronic function-limiting low back pain with or without lower extremity pain of at least 6 months duration (post-surgery); and patients who are competent to understand the study protocol and provide voluntary, written informed consent and participate in outcome measurements.

Inclusion criteria also included no evidence of facet joint pain and failure to improve substantially with conservative management including but not limited to physical therapy, chiropractic manipulation, exercises, drug therapy, bedrest, and fluoroscopically directed caudal or transforaminal epidural injections.

Exclusion criteria included facet joints, uncontrollable as sole pain generators, unstable or heavy opioid use (400 mg of morphine equivalents daily), uncontrolled psychiatric disorders, uncontrolled medical illness, any conditions that could interfere with the interpretation of the outcome assessments, pregnant

or lactating women, and patients with a history or potential for adverse reaction(s) to local anesthetic, steroids, or hypertonic sodium chloride solution.

Description of Interventions

All procedures were performed in a sterile operating room under sterile conditions utilizing fluoroscopy and a specially designed RK needle and a Racz catheter 19 gauge Brevi-STF.

Procedure

The procedure included appropriate preparation with interavenous access, antibiotic administration, and appropriate sedation.

An RK needle was introduced into the sacral epidural space under intermittent fluoroscopy. Once the needle placement was confirmed to be in the epidural space, a lumbar epidurogram was carried out, utilizing approximately 5 mL of contrast (Omnipaque® 240). Identification of the filling defects was carried out by examining the contrast flow into the nerve roots. Intravascular or subarachnoid placement of the needle or contrast was avoided; if such malpositioning occurred, the needle was repositioned.

In Group I, after the epidurography, a Racz catheter was passed through the RK needle up to S3 and additional Omnipaque 240, 3 mL, was injected. Following this, 5 mL of 2% preservative free Xylocaine was injected into the epidural space through the catheter.

In Group II, after identification of the filling defects, the Racz catheter was advanced through the RK needle to the area of filling defect or the site of pathology as determined by magnetic resonance im-

Table 1. Summary of steps and procedural considerations.

GROUP I (Control Group)	GROUP II (Intervention Group)
1. Preparation	1. Preparation
2. Epidurography	2. Epidurography
3. Introduction of catheter up to S3 or S2	3. Introduction of catheter to level of defect
4. No adhesiolysis	4. Adhesiolysis and/or targeted catheter positioning
5. Repeat epidurography	5. Epidurography with confirmation of ventral and lateral filling
6. Injection of 5 mL of 2% lidocaine	6. Injection of 5 mL of 2% lidocaine
7. Transfer to recovery room	7. Transfer to recovery room
8. Injection of 6 mL of normal saline	8. Injection of 6 mL of 10% sodium chloride solution
9. Injection of 6 mg of non-particulate betamethasone	9. Injection of 6 mg of non-particulate betamethasone
10. Injection of 1 mL of normal saline and removal of catheter	10. Injection of 1 mL of normal saline and removal of catheter

aging (MRI), computed tomography (CT), or symptomatology. Adhesiolysis was carried out and the final positioning was achieved in the epidural space laterally and ventrally. After satisfactory positioning, at least 3 mL of contrast was injected. If there was no subarachnoid, intravascular, or other extra epidural filling and satisfactory filling was obtained with epidural and targeted nerve root filling, 5 mL of 2% preservative free Xylocaine was injected either as a single dose in patients without hardware or fusion or was injected intermittently in other cases.

Following completion of the injection, the catheter was taped utilizing a bio-occlusive dressing.

Recovery Room

If no complications with motor weakness were observed after 10 to 15 minutes of lidocaine administration, injection of 6 mL of normal saline in Group I or 10% sodium chloride solution in Group II, in 2 divided doses of 3 mL each was completed. This was followed by injection of 6 mg of non-particulate Betamethasone and 1 mL of sodium chloride solution with removal of the catheter in both groups.

Repeat percutaneous adhesiolysis injections were provided after at least 3 months based on the response to the prior injections evaluated by improvement in physical and functional status and deterioration of pain relief below 50%.

Additional Interventions

All the patients underwent the treatments as assigned. A patient was unblinded on request or if an emergency situation existed. If a patient required additional procedures, they were provided based on the response to the previous injections, either after unblinding or without unblinding. If the patient chose not to be unblinded, the prior treatment was repeated as assigned. Patients who were non-responsive, but continued with conservative management were followed without further study procedures with medical management, unless they requested unblinding. In addition, all patients who were unblinded at any time and those who were lost to follow-up at one year were considered withdrawn.

Co-Interventions

Most patients were receiving opioid and non-opioid analgesics, adjuvant analgesics, and some were involved in a therapeutic exercise program. If patients were improving significantly and the medical neces-

sity for these drugs was lacking, medications were stopped or dosages were decreased. In addition, dosages were also increased based on medical necessity. All patients continued previously directed exercise programs, as well as their work. Thus, in this study, there was no specific physical therapy, occupational therapy, bracing, or other interventions offered other than the study intervention.

Objectives

The study was designed to evaluate the effectiveness of percutaneous adhesiolysis in managing chronic low back and/or lower extremity pain in patients with post lumbar surgery syndrome in providing effective and long-lasting pain relief and to evaluate the differences with adhesiolysis compared to fluoroscopically directed caudal epidural injections.

Outcomes

Multiple outcome measures were utilized including the NRS (0 – 10 scale), the ODI on a 0 – 50 scale, employment status, and opioid intake in terms of daily intake of morphine equivalents, with assessment at 3, 6, and 12 months post treatment. The value and validity of the NRS and ODI have been reported (76-81). Thresholds for the minimum clinically important difference for the ODI varied from a 4 to 15 point change from of a total score of 50. Significant pain relief was described as 50% or more reduction in the NRS from baseline, whereas significant improvement in function was described as at least a 40% reduction in the ODI (31,33-36,60,61,81-84).

Based on the dosage frequency and schedule of the drug, the opioid intake was converted into morphine equivalents (85).

Employment and work status were determined based on employability at the time of enrollment rather than including all patients in the study as employable. Employment and work status were classified into multiple categories such as employable, housewife with no desire to work outside the home, retired, or over the age 65. Patients who were unemployed due to pain or employed but on sick leave or laid off were considered as employable.

Sample Size

Sample size is calculated based on reduction of NRS. A 25% clinical difference change of 1.15 (d) was set from a previous study (51). With standard deviation (σ) of the NRS of 2.3, $\delta = d/\sigma$, $\delta = 0.50$, to achieve

an alpha of 0.05 and beta of 0.20 with 80% power (86), it required 60 patients in each group of the trial. One-hundred patients in each group would provide 95% power (i.e. alpha and beta of 0.05)

Previous studies of interventional techniques have confirmed that 50 to 60 patients is acceptable (82-84,87) None of the controlled studies thus far have included samples of more than 47 and they were also of mixed population (with or without surgery).

Randomization

From a total of 200 patients, 100 patients will be randomly assigned into each group.

Sequence Generation

Randomization was performed by computer generated random allocations sequence by simple randomization.

Allocation Concealment

The operating room nurse assisting with the procedure randomized the patients and prepared the drugs appropriately.

Implementation

Participants were invited to enroll in the study if they met inclusion criteria. One of the 3 nurses assigned as coordinators of the study enrolled the participants and assigned participants to their respective groups.

Blinding (Masking)

Participants and those administering the interventions were blinded to the group assignment. The blinding was assured by mixing the patients with other patients receiving routine treatment and not informing the physician performing the procedure of the inclusion of the patients in the study. However, blinding was considered inadequate in patients in Group I as the physician performing the procedure understood that Group I was a control group based on the catheter position, even though the injected drugs or the procedure was not revealed to other staff members.

All the patients completing one-year follow-up were selected by the statistician who was not participating in provision of patient care. The unblinding results were not disclosed to either the treating physician or other participants or patients. In this manner, the nature of blinding was not interrupted. Sixty consecutive patients per group were selected for data analysis and this report.

Statistical Methods

Statistical analysis included chi-squared statistic, Fisher's exact test, t-test, and paired t-test. Results were considered statistically significant if the P value was less than 0.05.

Chi-squared statistic was used to test the differences in proportions. Fisher's exact test was used whenever the expected value was less than 5; a paired t-test was used to compare the pre- and post-treatment results of average pain scores and ODI measurements at baseline versus 3, 6, and 12 months. For comparison of mean scores between groups a t-test was performed.

Intent-to-Treat-Analysis

An intent-to-treat-analysis was performed. Either the last follow-up data or initial data were utilized in the patients who dropped out of the study and no other data were available.

RESULTS

Participant Flow

Figure 1 illustrates the participant flow.

Recruitment

The recruitment period started in January 2006 and is ongoing.

Baseline Data

Baseline demographic and clinical characteristics of each group are illustrated in Table 2. There were no significant differences noted between the groups.

Analysis of Data

Numbers Analyzed

A schematic illustration of patient flow is provided in Fig. 1. The study period for the present report extended from January 2006 to August 2009 with selection of 120 patients with 60 patients in each group with completion of one-year follow-up.

Outcomes and Estimation

Pain Relief

Table 3 illustrates the NRS scores. Pain scores changed significantly from baseline at 3, 6, and 12 months in all groups, with significant differences between the groups, and baseline to follow-up periods.

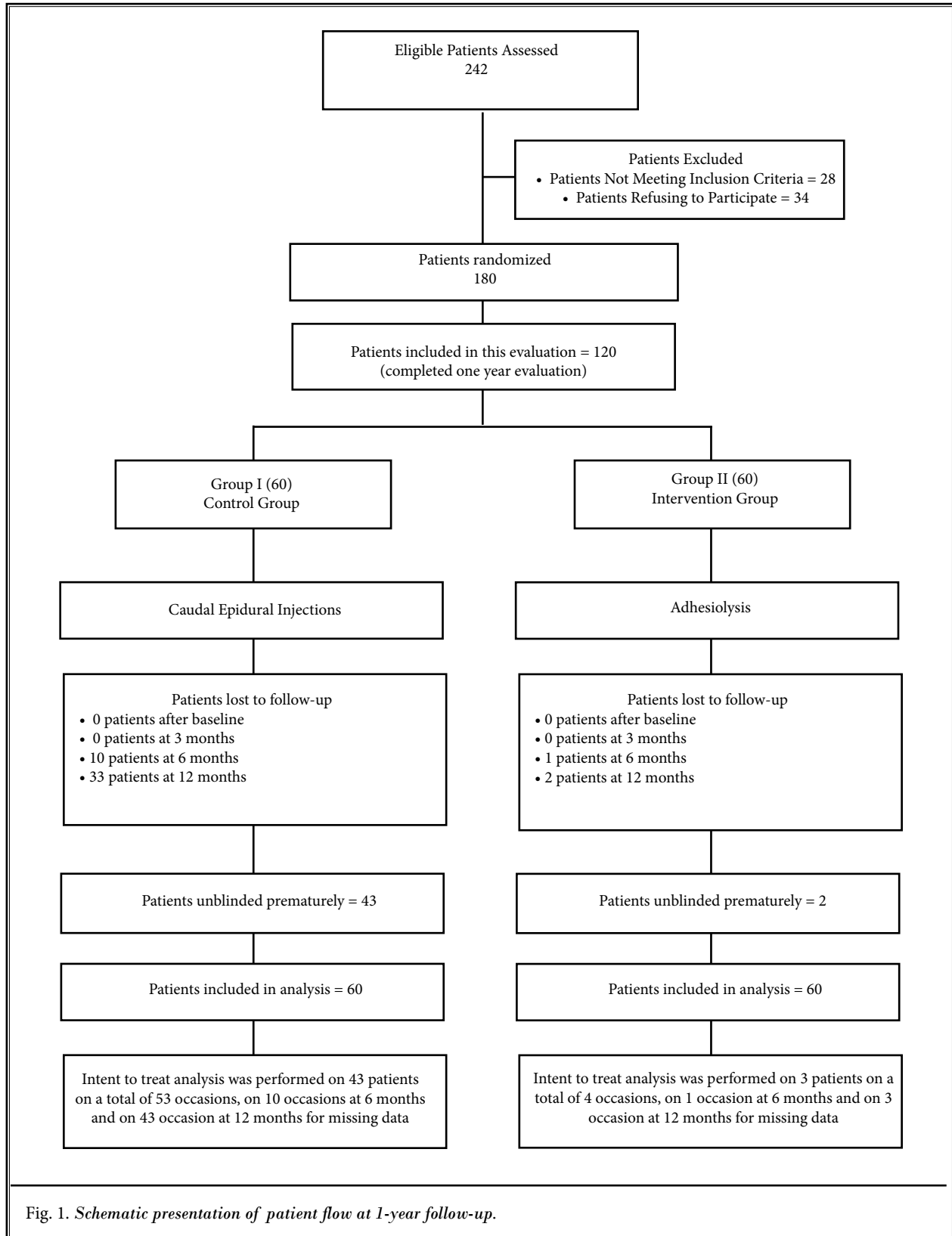


Fig. 1. Schematic presentation of patient flow at 1-year follow-up.

Table 2. Demographic characteristics.

		Group I (N = 60)	Group II (N = 60)	P value
Gender	Male	42% (25)	42% (25)	1.00
	Female	58% (35)	58% (35)	
Age	Mean ± SD	52 ± 13.9	52 ± 12.5	0.962
Height (inches)	Mean ± SD	67 ± 4.3	67 ± 4.0	0.807
Weight (lbs.)	Mean ± SD	185 ± 44.0	178 ± 50.1	0.458
Duration of pain (months)	Mean ± SD	186 ± 121.7	196 ± 109.4	0.642
Mode of onset of pain	Non-traumatic	55% (33)	57% (34)	0.540
	Traumatic	45% (27)	43% (26)	
Leg pain Distribution	Bilateral	39% (23)	35% (21)	0.926
	Left only	22% (13)	27% (16)	
	Left worse	10% (6)	8% (5)	
	Right only	27% (16)	23% (14)	
	Right worse	2% (1)	7% (4)	
Surgical history	One surgery	50% (30)	47% (28)	0.603
	Two surgeries	30% (18)	23% (14)	
	Three surgeries	10% (6)	17% (10)	
	> Three surgeries	10% (6)	13% (8)	
	Fusion	45% (27)	38% (23)	0.579

The proportion of patients with significant pain relief (≥ 50%) is illustrated in Fig. 2. There were significant differences between the groups and from baseline to various follow-up periods in both groups.

Functional Assessment

Functional assessment results assessed by the ODI are illustrated in Table 4 and Fig. 3.

Employment Characteristics

Table 5 demonstrates employment characteristics in both groups.

Opioid Intake

Table 6 illustrates opioid intake between both groups. There was a significant difference between Group I and Group II in intake of opioids with Group II patients taking higher amounts. However, there was no significant difference in the subsequent intake of opioids in Group I compared to baseline, whereas there were significant reductions in opioid intake at all follow-up periods in Group II compared to baseline.

Table 3. Pain relief characteristics.

		Group I (N = 60)	Group II (N = 60)	P value
Average pain scores (mean ± SD)	Baseline	7.9 ± 0.8	8.1 ± 0.8	0.224
	3 months	4.9# ± 1.6	3.4# ± 0.8	0.000
	6 months	5.8# ± 1.5	3.7# ± 1.1	0.000
	12 months	6.1# ± 1.4	4.0# ± 1.2	0.000

indicates significant difference with baseline values within group

Therapeutic Procedural Characteristics

Therapeutic procedural characteristics with average pain relief per procedure are illustrated in Table 7. Average overall relief per year was 13.1 ± 14.2 weeks in Group I and 41.2 ± 14.7 weeks in Group II, with significant differences between the groups. The average relief ranged from 5 to 9 weeks in Group I and 11 to 13 weeks in Group II with no significant difference noted between the relief of back and leg pain.

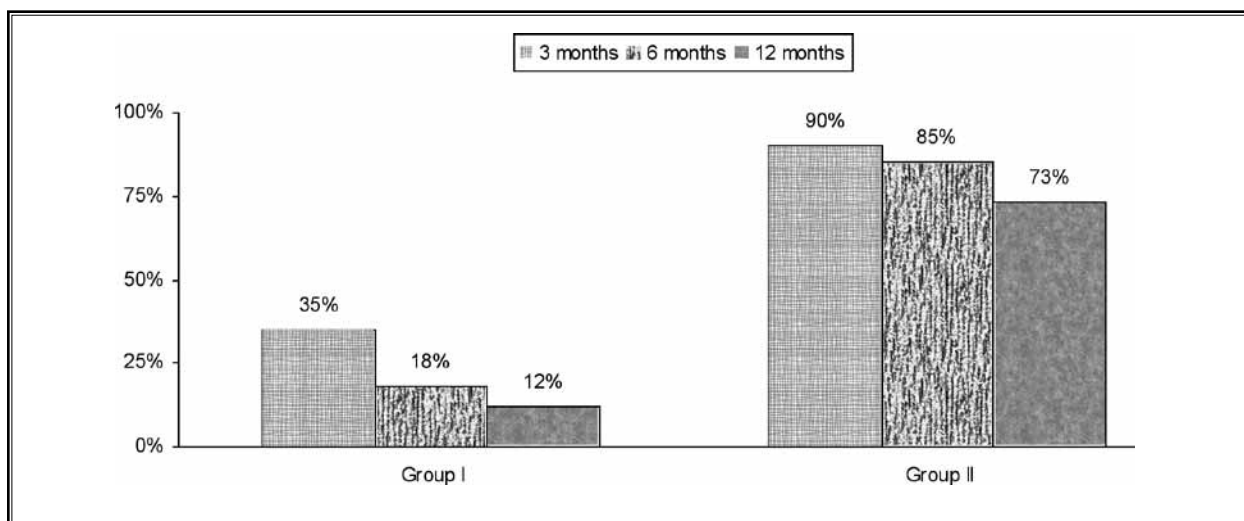


Fig. 2. Proportion of patients with significant relief of > 50%

Table 4. Functional assessment evaluated by Oswestry Disability Index.

		Group I (N = 60)	Group II (N = 60)	P value
Average Oswestry Disability Index (Mean ± SD)	Baseline	28.6 ± 4.1	31.2 ± 4.1	0.001
	3 months	20.2# ± 6.6	15.2# ± 4.1	0.000
	6 months	22.3# ± 6.1	15.2# ± 5.2	0.000
	12 months	23.3# ± 5.8	15.8# ± 5.6	0.000

indicates significant difference with baseline values within group

Adverse Events

There were no adverse events noted.

Discussion

Preliminary results of this study of 120 patients with chronic function limiting pain with lumbar post surgery syndrome showed significant pain relief (≥ 50%) in 73% of the patients and functional improvement (≥ 40% reduction in Oswestry scores) in 77% undergoing adhesiolysis (Group II) at one-year follow-up. Significant differences were observed between control group (Group I) and adhesiolysis group. In the

Table 5. Employment characteristics

Employment status	Group I		Group II	
	Baseline	12 months	Baseline	12 months
Employed part-time	3	3	1	1
Employed full-time	6	6	4	4
Unemployed	3	3	0	0
Total employed	9	9	5	5
Eligible for employment	12	12	5	5
Housewife	4	2	1	1
Disabled	28	28	42	41
Over 65 year of age	16	16	12	13
Total number of patients	60	60	60	60

In Group I – One full-time employee and one house-wife become disabled

In Group II – One unemployed become a full-time employee

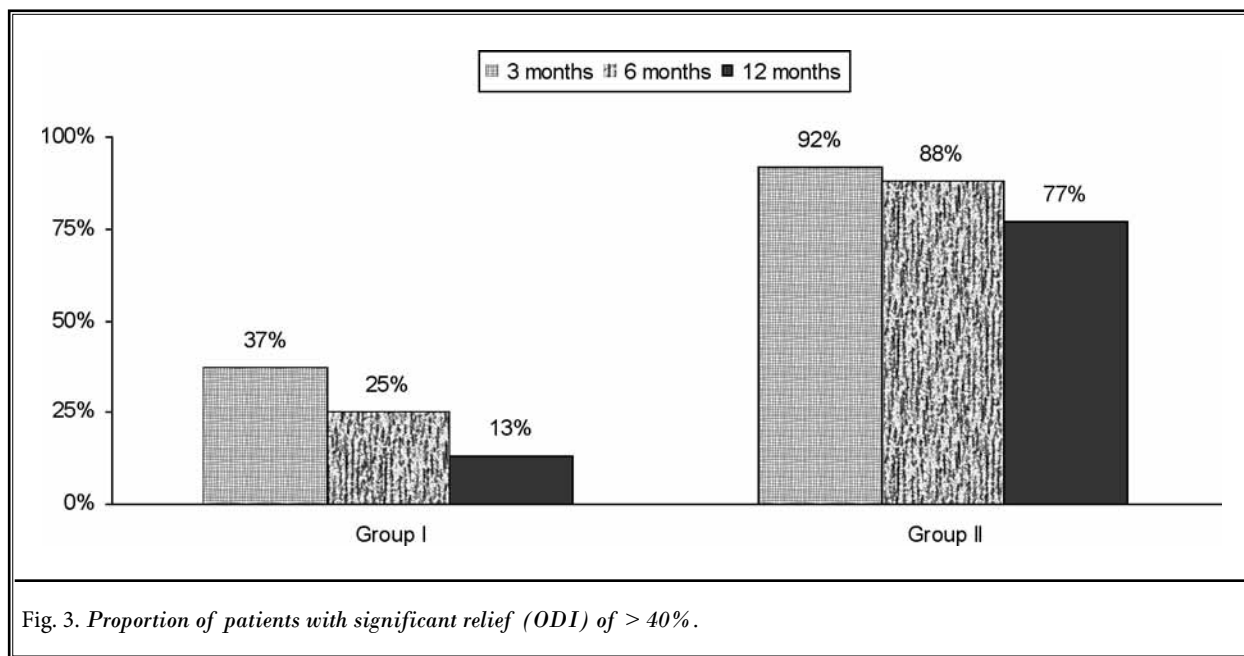


Fig. 3. Proportion of patients with significant relief (ODI) of > 40%.

control group significant relief was observed in 12% of patients with functional improvement in 13% of patients at one-year follow-up. The average procedures per year were 2.2 ± 1.1 in Group I and 3.5 ± 1.0 in Group II with an average total relief per year of 13.1 ± 14.2 weeks in Group I and 41.2 ± 14.7 weeks in Group II over a period of one year.

The results of this study illustrate the mechanism

Table 6. Daily opioid (morphine equivalents)

	Group I	Group II	P value
Baseline	41 ± 21.8	64 ± 45.1	0.001
3 months	42 ± 28.6	$42\# \pm 28.9$	0.667
6 months	47 ± 42.4	$49\# \pm 42.3$	0.709
12 months	40 ± 29.2	$41\# \pm 28.6$	0.715

indicates significant difference ($P < 0.05$) with baseline values

Table 7. Illustration of procedural characteristics with procedural frequency, average relief per procedure, and average total relief in weeks over a period of 1 year

	Back Pain		Leg Pain	
	Group I (N = 60)	Group II (N = 60)	Group I (N = 59)	Group II (N = 58)
1st injection relief	4.8 ± 4.3 (60)	$10.7^* \pm 3.8$ (60)	5.0 ± 4.4 (59)	$10.3^* \pm 4.1$ (58)
2nd injection relief	6.3 ± 4.5 (41)	$11.9^* \pm 3.7$ (56)	6.6 ± 4.4 (40)	$11.9^* \pm 3.8$ (54)
3rd injection relief	6.7 ± 4.6 (23)	$11.9^* \pm 2.8$ (52)	6.7 ± 4.6 (23)	$12.0^* \pm 2.8$ (50)
4th injection relief	8.9 ± 3.8 (10)	$12.5^* \pm 2.7$ (44)	8.9 ± 3.8 (10)	$12.5^* \pm 2.9$ (39)
Number of injections per year	2.2 ± 1.1	$3.5^* \pm 1.0$	2.2 ± 1.1	$3.5^* \pm 1.0$
Total relief per year (weeks)	13.1 ± 14.2 (60)	$41.2^* \pm 14.7$ (60)	13.6 ± 14.1 (59)	$40.7^* \pm 15.3$ (58)
Average relief per procedure	5.9 ± 4.5 (134)	$11.7^* \pm 3.4$ (212)	6.1 ± 4.5 (132)	$11.6^* \pm 3.5$ (204)

* indicates significant difference with group I ($P < 0.05$)

of percutaneous adhesiolysis with steroids and hypertonic saline to be superior to epidural steroid injection. The defined purpose of percutaneous epidural lysis of adhesions is to eliminate the deleterious effects of scar formation, with target delivery of high concentrations of injected drugs. Animal models of post lumbar laminectomy syndrome demonstrate epidural and perineural scarring and nerve root adherence to the underlying disc and pedicle (47-49,88-90).

With percutaneous adhesiolysis, in addition to adhesiolysis, there is the advantage of the actions of local anesthetics, steroids, and hypertonic sodium chloride solution. Neural blockade is postulated to exert its effects by altering or interrupting nociceptive input, the reflex mechanism of afferent fibers, the self-sustaining activity of the neurons, and the pattern of central neuronal activities (91,92). Corticosteroids have been shown to reduce inflammation by inhibiting the synthesis of a number of pro-inflammatory mediators (91,92). Local anesthetics also have been described to provide short- to long-term symptomatic relief based on various mechanisms, including suppression of nociceptive discharge, block of the sympathetic reflex arch, the block of sensitization, anti-inflammatory effect, and blockade of axonal transport of nerve fibers (93). Hypertonic sodium chloride solution has been shown to provide neurolysis and analgesia (50-58).

The results of this evaluation are similar to the previous evaluations (50,51,56). Of the 3 randomized trials included in the evidence synthesis by Epter et al (1), 2 studies (51,56) provided significant improvement in patients undergoing adhesiolysis at 12 months. The study by Heavner et al (50) compared various types of solutions used after mechanical adhesiolysis with all groups of patients receiving adhesiolysis. Manchikanti et al (51) showed adhesiolysis to be superior to epidural steroid injections. The results of the current study are similar to our previous study (51) with one-day adhesiolysis and a control group receiving epidural injections in a randomized double-blind equivalence trial. Thus, the results may not be compared with 3-day adhesiolysis done by others (50,56).

This study may be criticized for inadequate double-blinding, lack of a placebo group, and publication of preliminary results.

Patient blinding was considered adequate as patients were mixed together with other patients and the only occasion where blinding was not followed was in Group I, placing the catheter without adhesiolysis at S3. The chances of this complicating the results are minimal as all other personnel were blinded.

With the difficulties related to placebo groups in interventional techniques in the United States, the active control with local anesthetics and steroids without adhesiolysis is considered appropriate due to the increasing influence of comparative effectiveness research in modern medicine. Further, this study will provide generalizability and external validity better than a placebo-controlled trial. Finally, based on a sample size calculation, 60 patients is adequate in this extremely difficult population with a history of failed lumbar surgery and failure of all types of conservative management. Even then, this study includes one year follow-up of 60 patients in each group (sample size justification), which is the largest of any of the studies conducted thus far. The population included for post surgery syndrome exceeds the combined population of the previous randomized trials.

Another limitation is that the baseline average ODI scores and opioid intake were significantly different between Group I and Group II. We have no reason to account for these differences considering that the groups were randomized and these differences were not identifiable at follow-up periods.

This is a practical clinical trial, or an equivalence trial, which differs from placebo-controlled trials. Further, in the modern era, practical clinical trials measuring effectiveness are considered more appropriate than explanatory trials measuring efficacy (76,77,79,80,94-99). The differences between placebo-controlled trials and active-controlled trials include the fact that placebo-controlled trials measure absolute effect size and show the existence of effect, whereas active controlled trials, such as the present study, not only show the existence of effect, but compare the therapies (100). The cost effectiveness of this intervention also has been demonstrated showing that this procedure is safer and more cost effective than surgery, spinal cord stimulation, intrathecal implantables, or conservative medical management.

In summary, the evidence in this report demonstrates that in post surgery patients with chronic function-limiting recalcitrant low back and lower extremity pain, percutaneous adhesiolysis with hypertonic sodium chloride injection may provide on average 12 weeks of relief with each procedure and may provide as much as 42 weeks of relief over a period of one year with 3 to 4 treatments per year.

CONCLUSION

This study of the effectiveness of percutaneous adhesiolysis in lumbar post surgery syndrome demon-

strated effectiveness in 73% of patients with pain relief and improvement in functional status, compared to the control group receiving epidural injection with improvement seen in only 12% of patients at one-year follow-up.

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